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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/560,780

Applicant(s)

OKUNO ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with the application is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-6 are pending.
2. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed, *i.e.*, a DNA-polymorphism-based method for identifying field resistance of a rice plant to rice blast. Note that titles can be up to 500 characters long.
3. The abstract is not descriptive of the instant invention - the name of the G271 DNA marker should be in the abstract. Additionally, the wording is awkward and not in Standard English. A new abstract is required that is clearly indicative of the invention to which the claims are directed.
4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Objections

5. Claim 4 is objected to because the article before "genomic" in line 6 should be deleted.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to methods for identifying field resistance of a rice plant to rice blast and a method of breeding a rice variety with field resistance to rice blast, wherein the methods make use of a DNA marker linked to *pi21(t)*.

The instant specification, however, only provides guidance for extraction of rice genomic DNA (pg 12); RFLP analysis using RFLP markers or unknown composition obtained in an unknown manner from "STAFF" (pg 12-13); testing the F4 progeny from a cross between two unidentified Japanese rice varieties for field resistance to rice blast (pg 14-15); identification of RFLP markers, including G271, linked to QTLs associated with field resistance to rice blast (pg 16-17); and testing the linkage between G271 and rice blast resistance in other rice plants (pg 17). The putative gene associated with rice blast resistance was named *pi21(t)*, and it and G271 are 5 cM apart.

The instant specification fails to provide guidance for RFLP marker G271 for methods of using it in RAPD, CAPS, SSR or AFLP analysis, or for other DNA markers that are closely linked to *pi21(t)* and for methods of using them in RFLP, RAPD, CAPS, SSR or AFLP analysis.

The instant specification fails to provide guidance for exact hybridization or amplification conditions and probes/primers to use in methods of RFLP, RAPD, CAPS, SSR and AFLP analysis. The specification also fails to teach how to use a RFLP marker in RAPD, CAPS, SSR or AFLP analysis.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate

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methods for identifying field resistance of a rice plant to rice blast and a method of breeding a rice variety with field resistance to rice blast, wherein the methods make use of a DNA marker linked to *pi21(t)*.

Claims 2 and 5 are directed to use of DNA marker G271. Since the marker is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the marker is not so obtainable or available, a deposit of a microorganism containing a plasmid comprising said marker may satisfy the requirements of 35 USC 112. The specification does not disclose a repeatable process to obtain the marker and it is not apparent if the marker is readily available to the public. Thus, a deposit is required for enablement purposes.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Such a deposit would not enable methods of using the G271 marker in RAPD, CAPS, SSR, or AFLP analysis.

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8. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for identifying field resistance of a rice plant to rice blast by using a DNA marker that is closely linked to gene *pi21(t)* and to a method of breeding a rice blast resistant rice plant by using that DNA marker. In contrast, the specification does not describe any DNA marker so linked, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the markers are not described, the method of using the markers to identify rice blast field resistance of a rice plant and to breed a rice blast resistant rice plant is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus,

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visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the genus does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 lacks antecedent basis for the limitation "the rice" in line 3. Is the DNA extracted from the rice plant or the rice blast?

Claims 1 and 4 are indefinite in their recitation of "closely linked" in lines 4 and 8, respectively. It is unclear how "closely linked" differs from "linked", and what the cutoff point for close linkage is. Thus, the metes and bounds of the claim are unclear.

Claims 1 and 4, in their second step, provides for the use of a DNA marker to analysis polymorphism, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Similarly, active, positive method steps are missing from claims 3 and 6.

Claims 4 and 6 lack antecedent basis for the limitation "the polymorphism analysis".

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Claim 4 is indefinite in its recitation of "the gene is shown to be present from the first generation rice varieties or progenies thereof". The gene is not derived from the rice first generation varieties, but is derived from the first rice variety. Or does Applicant intend the phrase "from the ... thereof" to modify "selecting the individual"?

11. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The method involves extracting DNA from progeny [plants] of first generation rice varieties. The omitted steps are those involved in creating the progeny plants from the first generation rice varieties. Additionally, the word "progenies" should be replaced with --progeny-- in lines 7 and 12.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuoka et al (1996, International Rice Research Notes 21:50-51).

Fukuoka et al teach a method of identifying field resistance of a rice plant to rice blast that comprises extracting DNA from the plant and using DNA markers in a RFLP analysis, wherein the DNA markers are closely linked to *pi21(t)* because they map to chromosome 4 (pg 50, column 3; Figure).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuoka et al (1996, International Rice Research Notes 21:50-51).

The claims are drawn to a method of breeding a rice variety with field resistance to rice blast wherein the method comprises crossing a rice variety with resistance to one that does not have it, extracting DNA from the progeny, using DNA markers in a RFLP analysis, wherein the DNA markers are closely linked to *pi21(t)*, and selecting a plant that has the resistance gene.

The teachings of Fukuoka et al are discussed above. Fukuoka et al also teach crossing a resistant plant to a susceptible one (pg 50, column 3).

Fukuoka et al do not disclose selecting a plant that has the resistance gene.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of identifying via RFLP analysis blast resistance in the progeny of a cross between a susceptible plant and a resistant one as taught by Fukuoka et al, to select a plant that has the resistance gene. One of ordinary skill in the art would have been motivated to do so because of the interest in developing a rice plant with field resistance to blast (pg 50, paragraph spanning columns 1-2).

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15. Claims 2 and 5 are free of the prior art, given the failure of the prior art to teach or suggest DNA marker G271.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
January 17, 2003



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